5.0 510(k) SUMMARY

In accordance with Title 21 Code of Federal Regulations (21 CFR), Part 807, and in particular, §807.92, the following 510(k) summary is provided for the *VertiFlex™ Octane™ PEEK Vertebral Body Replacement* device:

5.1 Submitted By:

APR - 6 2007

VertiFlex™, Incorporated
1954 Kellogg Avenue, Suite 100
Carlsbad, California 92008

Contact: Steve Reitzler, Vice President of Regulatory & Quality Assurance

Date Prepared: December 22, 2006

5.2 Device Name

Trade or Proprietary Name:	*VertiFlex™ Octane™ PEEK Vertebral Body Replacement*
Common or Usual Name:	Vertebral Body Replacement Device
Classification Name:	Spinal intervertebral body fixation orthosis
Classification Regulation:	21 CFR, §888.3060
Product Code:	MQP

5.3 Predicate Devices

The subject device is substantially equivalent, in whole or in part, to the following commercially available predicate devices:

Interpore Cross *PEEK CAS* (K050861)
Quantum Orthopedics *Crystal™* and *Lucent™* (K062004)
Signus Medizintechnik *Curved Tetris™* (K041888)
Stryker Spine *AVS™ PL Spacer* (K062132)
Synthes *Vertebral Spacer* (K011037)

5.4 Device Description

The *VertiFlex™ Octane™ PEEK Vertebral Body Replacement,* or *PEEK VBR*, is an implant composed of pure Poly(Etheretherketone), or PEEK, intended to serve as a partial or total replacement of a vertebral body that is collapsed, damaged, or unstable as a result of tumor or trauma (i.e., fracture). The implant is available in a range of sizes, and is intended to achieve anterior decompression of the spinal cord and neural structures, and to restore vertebral height. In so doing, the device is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column. The device is hollow to permit packing with bone graft to facilitate fusion, but is of sufficient strength to provide column support even in the absence of fusion for prolonged periods. The device may be implanted by either conventional surgical methods, or via minimally-invasive techniques, using manual instrumentation provided by VertiFlex™, Inc., specifically for use with the subject device. The device is offered non-sterile.

5.5 Intended Use

The subject device is indicated for use as follows:

The VertiFlex™ PEEK VBR *is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture), to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The* VertiFlex™ PEEK VBR *is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. The interior of the* VertiFlex™ PEEK VBR *may be packed with bone graft.*

5.6 Comparison to Predicate Devices

Testing and comparisons of design characteristics and features have established that the subject *VertiFlex™ PEEK VBR* is substantially equivalent in design, materials of composition, indications, performance, and other features, to other vertebral body replacement devices commercially available in the U.S.

5.7 Summary of Non-Clinical Tests

Non-clinical tests, including those conducted in accordance with such recognized standards as ASTM F2077-03, *Test Methods for Intervertebral Body Fusion Devices*, have demonstrated the substantial equivalence of the subject device to commercially-available predicate devices in terms of performance.

5.8 Summary of Clinical Tests

No clinical testing was conducted to support this submission.

5.9 Conclusions

The results of all testing and comparison demonstrated the substantial equivalence of the subject device to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 6 2007

Vertiflex, Incorporated
% Mr. Steve Reitzler
Vice President, Regulatory and Quality Assurance
1954 Kellogg Avenue, Suite 100
Carlsbad, California 92008

Re: K070218
Trade/Device Name: *VertiFlex™ Octane™ PEEK Vertebral Body Replacement*
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: March 20, 2007
Received: March 22, 2007

Dear Mr. Reitzler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070218

Device Name: Vertiflex Octane PEEK Vertebral Body Replacement

Indications For Use: The VertiFlex™ PEEK VBR is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture), to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The VertiFlex™ PEEK VBR is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period. The interior of the VertiFlex™ PEEK VBR may be packed with bone graft.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Clarence Pruitt

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070218